PCT/IL04/000940

IL04/940

מדינת ישראל
STATE OF ISRAEL

Ministry of Justice
Patent Office

משרד המשפטים
לשכת הפטנטים

BEST AVAILABLE COPY

This is to certify that annexed hereto is a true copy of the documents as originally deposited with the patent application particulars of which are specified on the first page of the annex.

זאת לתעודה כי רצופים בזה העתקים נכונים של המסמכים שהופקדו לכתחילה עם הבקשה לפטנט לפי הפרטים הרשומים בעמוד הראשון של הנספח.

This 25 -10- 2004 היום

לספרי
על הבוחנים
רשם הפטנטים

Commissioner of Patents

נתאשר
Certified

לשימוש הלשכה
For Office Use

158379	מספר: Number
13 -10- 2003	תאריך: Date
	הוקדם/נדחה: Ante/Post-dated

רשם הפטנטים
13 -10- 2003
נ ת ק ב ל

חוק הפטנטים, תשכ״ז – 1967
PATENTS LAW, 5727-1967

בקשה לפטנט
Application For Patent

אני, (שם המבקש, מענו ולגבי גוף מאוגד - מקום התאגדותו)
I, (Name and address of applicant, and in case of body corporate-place of incorporation)

וולורין ישראל בע״מ (חברה ישראלית), קרית התקשורת נוה אילן, ד.נ. הרי יהודה מיקוד 90850, ח.פ. 513170142
Volurine Israel Ltd. (an Israeli company), Communications Center, Neve Ilan, Harey Yehuda 90850

בעל אמצאה מכוח Owner, by virtue of — הדין Operation of Law — ששמה הוא of an invention the title of which is

(בעברית) (Hebrew)
התקן לניטור לא חודרני של שלפוחית השתן למניעת הרטבה לא מבוקרת, ושיטת הפעלה עבורו

(באנגלית) (English)
Non Invasive bladder distension monitoring apparatus to prevent enuresis, and method of operation therefor

Hereby apply for a patent to be granted to me in respect thereof. — מבקש בזאת כי ינתן לי עליה פטנט

* בקשת חלוקה Application of Division	* בקשת פטנט מוסף Appl. for Patent of Addition	דרישת דין קדימה* Priority Claim		
מבקשת פטנט from application	* לבקשה/לפטנט to Patent/Appl.	מספר/סימן Number/Mark	תאריך Date	מדינת האיגוד Convention Country
No. ____ מס׳	No. ____ מס׳			
Dated מיום	Dated מיום			
* יפוי כח:				
המען למסירת מסמכים בישראל Address for Service in Israel וולורין ישראל בע״מ קרית התקשורת נוה אילן ד.נ. הרי יהודה, 90850				

חתימת המבקש Signature of Applicant	היום This 13 בחודש of אוקטובר שנת Year 2003
For the Applicants: וולורין ישראל בע״מ גיורא גורן מנכ״ל	

לשימוש הלשכה
For Office Use

טופס זה כשהוא מוטבע בחותם לשכת הפטנטים ומושלם במספר ובתאריך ההגשה, הנו אישור להגשת הבקשה שפרטיה רשומים לעיל.
This form, impressed with the Seal of the Patent Office and indicating the number and date of filing, certifies the filing of the application the particulars of which are set out above.

* מחק את המיותר
Delete whatever is inapplicable

התקן לניטור לא חודרני של שלפוחית השתן למניעת הרטבה לא מבוקרת, ושיטת הפעלה עבורו

Non Invasive bladder distension monitoring apparatus to prevent enuresis, and method of operation therefor

NON-INVASIVE BLADDER DISTENSION MONITORING ULTRASOUND APPARATUS

Field of the Invention

The invention is in the field of non-invasive bladder distension monitoring in general and for the prevention of enuresis in particular.

Background of the Invention

Enuresis affects not only young children becoming "dry" and elderly people who have lost bladder control but also post-operative patients, patients suffering from spinal cord or head injuries, benign prostate hypertrophy sufferers, and the like. Prevention of enuresis is complicated due to the fact that a subject typically has different daytime and night functional capacities, and moreover functional capacity is affected by a subject's posture, medications he may be taking, and the like.

Non-invasive bladder distension monitoring apparatus is illustrated and described *inter alia* US Patent No. 4,926,871 to Ganguly et al., US Patent No. 5,058,591 to Companion et al., US Patent No. 5,235,985 to McMorrow et al., US Patent No. 6,110,111 to Barnard, US Patent No. 6,213,949 to Ganguly et al., US Patent No. 6,579,247 to Abramovitch et al., and WO 03/039343 in the name of The Proctor & Gamble Company.

Summary of the Invention

The present invention is based on the premise that a subject's smooth front and rear bladder walls reflect impinging ultrasound energy at a considerably greater intensity than surrounding body tissues. And moreover, the average velocity of ultrasound energy in a human body is about 1500 m/sec such that the round trip propagation time for externally applied ultrasound energy to a subject's bladder and back therefrom is in the range of 25-75 μsec and 80-200 μsec for a subject's front and rear bladder walls.

The present invention includes (a) an ultrasound transceiver unit for intimate juxtaposition on a subject's bare lower abdomen for transmitting ultrasound energy frequency, on a long pulse regime or continuous pulse regime, modulated in accordance with a sweep function for sonically irradiating the subject's bladder and simultaneously receiving ultrasound energy reflected therefrom; and (b) a controller for determining clinical information from the waveform of the difference between the instantaneous frequencies of the ultrasound energies simultaneously transmitted by and received at the ultrasound transceiver unit. The clinical information may include one or more of the following parameters: an instantaneous intra bladder wall separation between a subject's front and rear bladder walls, an instantaneous bladder wall thickness of at least one of a subject's front and rear bladder walls, and an instantaneous bladder wall compliance of at least one of a subject's front and rear bladder walls. The intra bladder wall separation is preferably measured between a bladder's inside surfaces as opposed to its outside surfaces since the former more accurately correlates to its urine volume.

The present invention is suitable for monitoring bladder distension for various clinical applications, and is particularly suitable for selectively issuing an alarm signal to prevent enuresis in the instance that a subject's bladder satisfies a predetermined bladder distension condition, for example, his instantaneous intra bladder wall separation is at least equal to a predetermined minimum separation, or alternatively a function of two or more different predetermined bladder distension conditions. The present invention can be readily implemented to satisfy the needs of different populations suffering from enuresis as follows: First, the present invention can be implemented as a miniaturized portable standalone device for placing on a subject's bare lower abdomen for issuing, for example, vibratory alarms to the subject himself. Second, the present invention can be implemented as a base ultrasound transceiver unit for placing on a subject's bare lower abdomen, and an alarm unit in remote communication with its base ultrasound transceiver unit for issuing alarms to the subject himself, a

parent, an orderly, and the like. The alarm unit may be configured as a wristwatch, a beeper-like device, and the like. And third, the present invention can be implemented for deployment in hospital wards, old age people homes, and the like, in the form of a central station in remote communication with a multitude of base ultrasound transceiver units each intended for placing on a subject's bare lower abdomen and individually communicating with the central station.

Brief Description of the Drawings

In order to understand the invention and to see how it can be carried out in practice, a preferred embodiment will now be described, by way of a non-limiting example only, with reference to the accompanying drawings in which similar parts are likewise numbered, and in which:

Fig. 1 is a pictorial representation of a miniaturized portable standalone device for issuing alarm signals to a subject himself;

Fig. 2 is a pictorial representation showing deployment of the device of Figure 1 on a subject's lower abdomen for measuring his instantaneous intra bladder wall separation;

Fig. 3 is a block diagram of the device of Figure 1; and

Fig. 4 is a graph showing an exemplary waveform of the difference f1(t)-f2(t) between the instantaneous frequencies of the ultrasound energies simultaneously transmitted by and received at the device of Figure 1 in the case of a symmetrical saw tooth sweep function.

Detailed Description of the Preferred Embodiment

Figure 1 shows a standalone device 1 held in place on a subject's bare lower abdomen by a dual adhesive sided elastomeric patch 2 for issuing him an alarm signal in the instance that his bladder satisfies a predetermined bladder distension condition, for example, a predetermined minimum intra bladder wall separation IBWS between the inner surfaces of his front bladder wall FBW and

rear bladder wall RBW (see Figure 2). The device 1 has a lower surface 3 for intimate juxtaposition against a subject's bare lower abdomen, and a top surface 4 facing away therefrom and having a user interface 6 with an ON/OFF button 7, a CALIBRATION MODE pushbutton 8 for invoking a calibration mode of operation determining a subject's baseline intra bladder wall separation for calibrating the device 1, and an ALARM MODE pushbutton 9 for invoking a monitoring mode of operation for selectively issuing alarm signals.

Calibration of the device 1 with respect to a particular subject may be effected in accordance with either a so-called dry calibration procedure when he can indicate that he has a strong urge to void or a so-called wet calibration procedure when he involuntarily voids his bladder. The device 1 may also include an I/O interface, for example, RS-232, for enabling, for example, the input of a subject's baseline intra bladder wall separation at a particular location of the device as measured by other means, and outputting a data log of a subject's instantaneous intra bladder wall separation. The user interface 6 may also include a user operated selector 11 for selecting a particular bladder distension condition from a plurality of bladder distension conditions, for example, the selector 11 may have three settings L, M, H for specifying that the device should issue an alarm signal in the event that a subject's instantaneous intra bladder wall separation reaches 50%, 65% or 80% respectively, of his baseline intra bladder wall separation.

Figure 3 shows that the device 1 includes an ultrasound transceiver unit 12 and a controller 13 for selectively operating an alarm unit 14 for issuing, say, vibratory alarms to a subject. The transceiver unit 12 may include a single dual element ultrasound transducer having two independent piezoelectric elements 16 and 17, the former employed for transmitting ultrasound energy and the latter employed for receiving ultrasound energy. Alternatively, the transceiver unit 12 may include two or more ultrasound transducers. The transceiver unit 12 preferably employs one or more ultrasound transducers with a resonance

frequency in the region of about 1MHz, and a relatively low Q factor of about <40, and preferably <15.

The transceiver unit 12 includes a battery 18, and a frequency modulator 19 for controlling a generator 21 energizing the piezoelectric element 16 to transmit long pulses and or continuously of ultrasound energy f1(t) whose pulse duration PD is longer than the longer of the afore-mentioned round trip propagation times of 200*2 μsec for sonically irradiating a subject's bladder such that the transceiver unit 12 simultaneously transmits and receives ultrasound energy. The long pulses of ultrasound energy are frequency modulated in accordance with a sweep function between a minimum sweep frequency $f_{s,min}$ and a maximum sweep frequency $f_{s,max}$, and a cycle time CT (see Figure 4). As will become apparent hereinbelow, the greater the difference $f_{s,max}$-$f_{s,min}$, and the longer cycle time CT the greater the resolution of the device 1 for determining depths. Possible sweep functions include *inter alia* a symmetrical and or non-symmetrical saw tooth function, a sinusoidal function, continuously and or intermittently, and the like.. The transceiver unit 12 preferably transmits long pulses of ultrasound energy in long pulse mode as opposed to continuous mode to conserve battery power.

The transceiver unit 12 includes a receiver 22 for receiving reflected ultrasound energy f2(t) which is identically frequency modulated as the transmitted ultrasound energy f1(t) but lags behind the latter by a time interval Δt, and a frequency analyzer 23 for analyzing the waveform of the difference between the instantaneous frequencies f1(t) and f2(t) of the ultrasound energies simultaneously transmitted by and received at the transceiver unit 12 (see Figure 4). In the case of a symmetrical saw tooth sweep function, the difference f1(t)-f2(t) leads to a constant difference ΔF for a given depth of a subject's anatomical structure, namely, his front bladder wall FBW or his rear bladder wall RBW except for the intervals when f2(t) $\geq$f1(t). For example, in the case that a sweep function has a minimum sweep frequency $f_{s,min}$ = 800kHz, a maximum sweep frequency $f_{s,max}$ = 1200kHz, and a cycle time CT = 400μsec, then the rate of

change of the frequencies f1(t) and f2(t) is 1 Hz/μsec. Thus, in the case $\Delta F = 60$ kHz, the propagation time of the reflected ultrasound energy from the anatomical structure effecting the reflection to reach the device 1 is half that, namely, 30 μsec corresponding to a depth of 1500 m/sec x 30 μsec = 45 mm.

Operation of the device 1 is now described:

A subject places the device on his bare lower abdomen, switches it on, and presses the CALIBRATION MODE pushbutton once to invoke the calibration mode of operation. The subject presses the CALIBRATION MODE pushbutton twice when he has a strong urge to void or he involuntarily voids, and the device calculates his baseline intra bladder wall separation from the measurements D2-D1. The device is now calibrated for that subject and is ready for use. In operation, the subject presses the ALARM MODE pushbutton and sets the selector switch to, say, its M setting such that the device issues an alarm signal in the event that his instantaneous intra bladder wall separation reaches 70% of his baseline intra bladder wall separation.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications, and other applications of the invention can be made within the scope of the appended claims. For example, a transceiver unit may transmit long pulses of ultrasound energy frequency modulated in accordance with different sweep functions for determining different clinical information regarding a subject's bladder. Similarly, a transceiver unit may transmit long pulses of ultrasound energy of different pulse durations for determining different clinical information regarding a subject's bladder.

Claims:

1. Non-invasive bladder distension monitoring ultrasound apparatus comprising:

(a) an ultrasound transceiver unit, and or an array of two or more transceiver units, for intimate juxtaposition on a subject's bare lower abdomen for transmitting a long pulse of ultrasound energy frequency modulated in accordance with a sweep function for sonically irradiating the subject's bladder and simultaneously receiving ultrasound energy reflected therefrom; and

(b) a controller for determining clinical information from the waveform of the difference between the instantaneous frequencies of the ultrasound energies simultaneously transmitted by and received at said ultrasound transceiver unit.

2. Apparatus according to claim 1 wherein said clinical information includes one or more straight lines measurements from said ultrasound transceiver unit to a surface of a subject's bladder.

3. Apparatus according to claim 2 wherein said clinical information is an instantaneous intra bladder wall separation between a subject's front and rear bladder walls.

4. Apparatus according to claim 2 wherein said clinical information is an instantaneous bladder wall thickness of at least one of a subject's front and rear bladder walls.

5. Apparatus according to any one of claims 1 to 4 wherein said clinical information is an instantaneous bladder wall compliance of at least one of a subject's front and rear bladder walls.

6. Apparatus according to any one of claims 1 to 5 wherein said transceiver unit transmits long pulses and or continuously of ultrasound energy frequency modulated in accordance with different sweep functions for determining different clinical information regarding a subject's bladder.

7. Non-invasive bladder distension monitoring method comprising the steps of:

(a) providing an ultrasound transceiver unit for intimate juxtaposition on a subject's bare lower abdomen for transmitting a long pulse of ultrasound energy frequency modulated in accordance with a sweep function for sonically irradiating the subject's bladder and simultaneously receiving ultrasound energy reflected therefrom; and

(b) determining clinical information from the waveform of the difference between the instantaneous frequencies of the ultrasound energies. simultaneously transmitted by and received at the ultrasound transceiver unit.

8. The method according to claim 7 wherein the clinical information includes one or more straight lines measurements from the ultrasound transceiver unit to a surface of a subject's bladder.

9. The method according to claim 8 wherein the clinical information is an intra bladder wall separation between locations on a subject's front and rear bladder walls.

10. The method according to claim 8 wherein the clinical information is an bladder wall thickness of at least one of a subject's front and rear bladder walls.

11. The method according to any one of claims 7 to 10 wherein the clinical information is a bladder wall compliance of at least one of a subject's front and rear bladder walls.

12. The method according to any one of claims 7 to 11 wherein step (a) includes transmitting long pulses of ultrasound energy frequency modulated in accordance with different sweep functions for determining different clinical information regarding a subject's bladder.

Respectfully submitted,

Volurine Israel Ltd

וולורין ישראל בע"מ

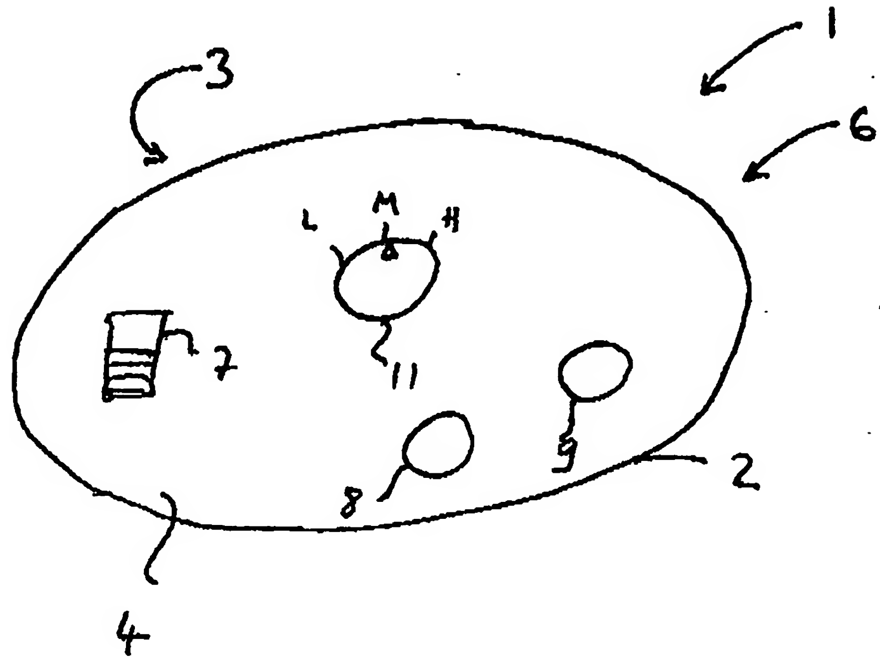

FIG. 1

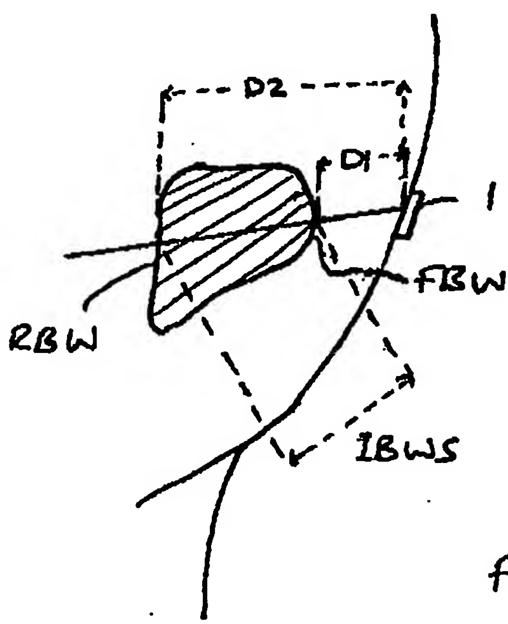

FIG. 2

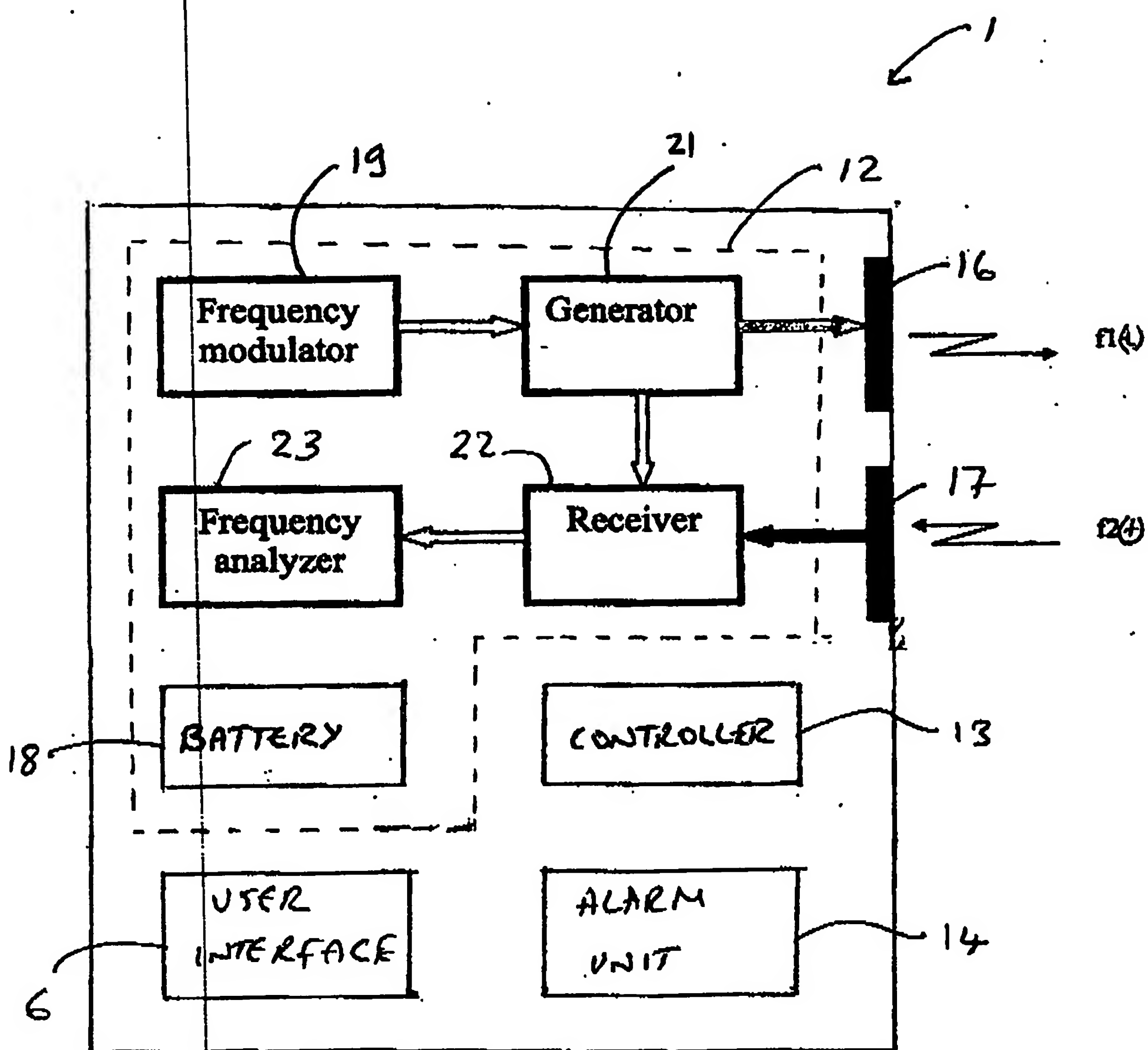
1
19
21
12
16
Frequency modulator
Generator
f1(A)
23
22
17
Frequency analyzer
Receiver
f2(t)
BATTERY
CONTROLLER
13
18
USER INTERFACE
ALARM UNIT
14
6

FIG. 3

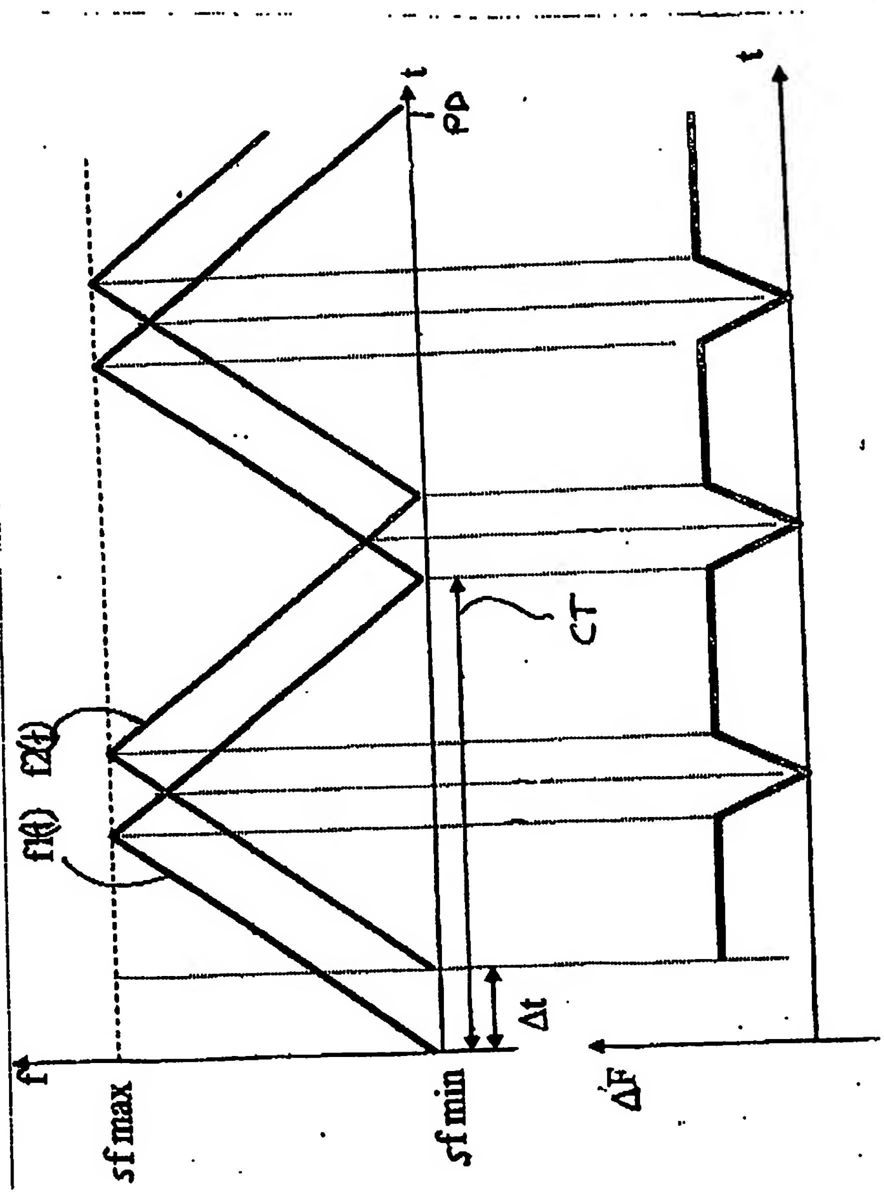

FIG. 4

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/IL04/000940

International filing date: 13 October 2004 (13.10.2004)

Document type: Certified copy of priority document

Document details: Country/Office: IL
Number: 158379
Filing date: 13 October 2003 (13.10.2003)

Date of receipt at the International Bureau: 23 November 2004 (23.11.2004)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)